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Visual quality with corneo-scleral contact lenses after intracorneal ring segment (ICRS) implantation for keratoconus management

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ABSTRACT

Purpose: To evaluate the visual quality results when fitting a corneo-scleral contact lens (CScL) after intracorneal ring segment (ICRS) implantation for keratoconus management.
Methods: Twenty-seven eyes of 27 patients with keratoconus underwent ICRS implantation and had CScL fitted as their visual quality was unsatisfactory with their spectacles or contact lenses. Patients received a complete eye examination, refraction and visual acuity assessment, anterior eye biomicroscopy, ocular fundus examination, corneal topographic analysis, endothelial-cell count, and visual quality assessment using contrast sensitivity and aberrometry tests. A diagnostic trial set was used in the fitting process, and patients were assessed according to a standardised methodology, including subjective visual quality and comfort, and contact lens usage time. The follow-up period was one year.
Results: After fitting CScL, log-MAR visual acuity values improved significantly in relation to the best spectacle-corrected vision (0.22 ± 0.17 vs 0.00 ± 0.12; $p < 0.001$). Total high-order aberrations decreased 33% (2.62 ± 1.31 vs 1.75 ± 1.81 µm; $p < 0.009$) and the spatial frequencies of contrast sensitivity all improved (all $p < 0.05$). Furthermore, 70.37% of patients reported high ratings of subjective visual quality (favourable and very favourable) and prolonged usage times (11.78 ± 3.93 h). After wearing CScL for one year, no adverse ocular effects or clinically relevant changes in corneal parameters, visual quality, comfort ratings or usage time were found.
Conclusion: This CScL appears to be an alternative reasonable option for keratoconic eyes with ICRS placement, providing an improvement in subjective visual quality.

1. Introduction

Additive surgical procedures, such as intrastromal corneal ring segment (ICRS) placement, are an option to treat keratoconus [1–10]. Intrastromal corneal ring segments are small pieces of synthetic material (semi-circular ring segments) that are inserted deep in the corneal stroma. They act as spacer elements between the corneal lamellae producing an "arc-shortening effect" which results in a flattening of the central cornea, so they were initially used for the correction of low and moderate myopia in normal eyes [11]. Implantation of ICRS in keratoconic eyes results in an improvement in the central corneal contour, a decrease in asymmetrical astigmatism, and refractive correction, thereby improving visual acuity and contact lens tolerance. In addition, they may delay or eliminate the need for keratoplasty [1–10].

It should be noted that after ICRS implantation there are still patients who need some type of visual correction to improve their eyesight [7–10]. Nonsurgical options to improve vision after ICRS implantation include different types of contact lenses, such as conventional or customised soft lenses and rigid gas-permeable (RGP; corneal, corneo-scleral and scleral) lenses, hybrid lenses and a piggyback contact lens system [12–26].

An advantage of RGP lenses is that they are able to mask corneal surface irregularities with the tear layer between the lens and anterior corneal surface, and they also provide a regular refractive surface [27,28]. Therefore, they are a successful option to achieve an improvement in visual quality, since they can compensate for a great number of high-order aberrations (HOAs) [29,30].

Corneo-scleral contact lenses (CScL) are RGP lenses that rest partly on the cornea and the conjunctival tissue overlaying the sclera. These lenses may be a good alternative option for improving comfort and

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visual quality when patients occasionally present intolerance to corneal RGP lenses or encounter insertion difficulty with scleral lenses. In addition, they provide a significant improvement in visual quality and comfort in cases of irregular corneas (such as keratoconic eyes and eyes that have undergone LASIK surgery), offering a better quality of life for these patients [29,30]. It should be noted that after ICRS implantation, significant changes in both the anterior and posterior corneal surfaces occur, therefore visual quality could be significantly affected because of the additional corneal irregularity induced by the implant.

To the best of our knowledge, although there are studies in the scientific literature on fitting RGP contact lenses on keratoconic eyes with ICRS implants, these have only assessed a small number of eyes (in particular for corneo-scleral or scleral lenses) [16–22]. Therefore, the aim of this study is to ascertain the outcomes of fitting a CScL in keratoconic eyes with ICRS implants, and to establish to what extent they can provide an improvement in visual quality.

2. Patients and methods

2.1. Patients

The sample of this study included 27 eyes of 27 patients who had Keraring (Mediphacos, Belo Horizonte, Brazil) ICRS implanted for keratoconus management. Keraring rings are triangular segments, which were implanted using mechanical or femtosecond laser-assisted techniques. In all cases, there was an optic zone of 5 mm, and the arc length and thickness depended on the results of a nomogram performed beforehand indicating the appropriate ring segment features. An ophthalmologist specialising in this technique carried out the procedure and selected the appropriate ring segment in each individual case and calculated the implantation parameters (see Fig.1).

On an average of 10 months (range 6–14 months) after ICRS implantation, these patients presented unsatisfactory visual quality with their spectacles (15 patients) or contact lenses (7 patients using soft toric lenses, 2 soft spherical lenses, and 3 corneal RGP lenses), therefore they were advised to have a new CScL fitted with a multi-aspherical geometry design. This unsatisfactory visual quality was not related to complications in the surgical procedure. None of the patients had ocular-surface disease, allergies, systemic disease, used medications that would have interfered with contact lens wear, or had undergone any ocular surgery (except ICRS implantation). This study protocol adhered to the tenets of the Declaration of Helsinki and it complies with the ethical requirements established by the University of Valencia.

Fig. 1. Corneal image of the eye implanted with a 200 μm Keraring intracorneal ring segment.

2.2. Data collection

First of all, patients underwent a comprehensive eye examination at the FISABIO Oftalmología Médica (Ophthalmology Centre) with a view to fitting CScL. If they were using other contact lenses, they were instructed to stop wearing them for at least 15 days beforehand. The exam included measuring the best spectacle-corrected visual acuity, the anterior segment ocular evaluation with the Visante optical coherence tomography system (Carl Zeiss Meditec, Inc. Dublin, CA, USA) and biomicroscopy, and ocular fundus examination with ophthalmoscopy. The corneal topographic analysis was obtained with the Pentacam HR Eye Scanner (Oculus Inc., Wetzlar, Germany) and the endothelial-cell count with a specular microscope (SP-3000P, Topcon Medical Systems Inc., Japan).

Data on the subjective and objective visual quality were collected using the Vision Contrast Test System (VCTS 6000, Vistech Consultants Inc., Dayton, OH, USA), and ocular aberrations were determined with the Alcon LADARWave (Custom Cornea Wavefront System, Alcon Laboratories Inc, Ft Worth, Texas, USA), respectively. The VCTS 6000 test was performed at a testing distance of 3 m, under photopic conditions of 85 cd/m^2 with the monocular full correction of patients in place, following the guidelines of the manufacturer. The ocular aberrometry test was performed in a dark room under monocular conditions on a pupil size of 6 mm. Pharmacological intervention for mydriasis (1% tropicamide eye drops) was used to achieve this pupil diameter. Ocular aberrometry data included the root mean square in terms of micrometres of deviation of defocus, astigmatism, coma aberration, spherical aberration and other HOAs.

The measurements were carried out before and after fitting the contact lens, and after one year of contact lens wear, following the same procedure as in our previous study for fitting the same contact lenses on keratoconic eyes without ICRS placement [30]. In all sessions, the devices were previously calibrated and the measurements were performed by professionals who were expert in handling them.

2.3. Contact lens used and fitting procedure

Patients were fitted with a CScL (Scleracon, Lenticon, Madrid, Spain) with a multi-aspherical geometry design based on three curves: the base curve, the intermediate or small transition curve, and the peripheral or scleral curve. These contact lenses are made of fluorosilicone acrylate (Optimum extreme; Contamac Ltd, Saffron Walden, UK) which is a highly gas-permeable material. Its oxygen permeability (ISO) is 125×10^{-11} (cm^2/sec) (mlO2)/(ml x mmHg). The average central thickness of this lens is around 0.27 mm and the fitting parameters are as follow: diameter ranges from 12.60 to 13.50 mm, base curves range from 5.80 to 9.20 mm (in 0.5 mm steps), peripheral or scleral curves range from 5.60 to 11.4 mm (in 0.10 mm steps), and power from + 20.00 to – 25.00 D (in 0.25 D steps).

The same procedure as in our previous study for fitting CScL on keratoconic eyes without ICRS placement was followed in this study [30]. The trial-lens method with two steps to determine the appropriate lens (first, the back optic zone radius and then the peripheral curve) was used. Patients were monitored in accordance with a standardised fitting methodology [29,30]. The fluorescein test determined these parameters according to the best ratio between the posterior lens surface with the anterior corneal surface and scleral zone, as well as ascertaining if there was any corneal damage (presence of corneal staining). Data of these parameters were needed to manufacture the lenses.

A difference in fitting CScL in keratoconic eyes after ICRS placement is the additional corneal irregularity induced by the implant. Although

some flattening of central cornea occurs, the greatest flattening effect takes place in the mid-peripheral region of the cornea, directly over the ICRS placement, which gives rise to an abnormal artificial steepening of the peripheral cornea relative to the mid-periphery [12,18]. Therefore, an appropriate fit should show a slight alignment to minimal apical corneal clearance but avoid touching the apex or mid-periphery of the cornea at the steepening induced by the ICRS implant, while maintaining an excellent peripheral fit. The lens should present a good lens position with optimum lens movement (0.5 mm), and an adequate tear exchange with no compression on the limbus (since stem cells are located in this area) and/or the conjunctival vessels under the contact lens. It should be noted that, at all times there must be enough vault between the lens and the cornea to prevent problems or complications when the lens puts mechanical pressure on the cornea overlaying the rings; however, in some cases when fitting CScL, a slight "feather touch" on the apex and corneal mid-periphery may be well tolerated since these lenses do not usually move enough to irritate these zones.

When the manufactured lenses were received at the clinic, the patients were given their next appointment to verify the appropriate fit of the lenses. Changes to the back optic zone radius, peripheral curve radii, power, and overall diameter were made until the contact lens was considered optimal for dispensing. At the end of the fitting process, after 8 h of CScL wear, a good lens position with optimal lens movement and an adequate tear exchange with no compression on the limbus or conjunctival tissue overlaying the sclera were observed. In addition, no adverse ocular events were found (no grade of corneal staining was seen). The number of contact lenses required and visits made until achieving the optimal lens are also reported.

Subsequently, to compare the improvement in visual quality before and after fitting these contact lenses, visual acuity, contrast sensitivity, and ocular aberrations (on a pupil size of 6 mm with pharmacological intervention for mydriasis) were measured. Furthermore, data for subjective comfort on a typical five-level Likert scale (1, very uncomfortable; 2, uncomfortable; 3, neither uncomfortable nor comfortable; 4, comfortable; and 5, very comfortable), subjective visual quality on a typical five-level Likert rating system (1, very poor; 2, poor; 3, neither poor nor favourable; 4, favourable; and 5, very favourable), and contact-lens wear time were also reported. Table 1 shows the criteria for successful fitting of this contact lens. The criteria for wearing time as a measure of success was based on the study by Ortenberg et al [31].

After 1 year, the lenses were again checked when the patient had been wearing them for at least 8 h. This was to see whether there were any differences in visual quality and corneal integrity when wearing these contact lenses for 1 year.

2.4. Data analysis

The SPSS 15.0 software (SPSS Inc., Chicago, IL, USA) was used for descriptive statistics, which quantified the means ± standard deviations (SD) of the study variables. The Kolmogorov-Smirnov test was calculated to determine the normality of the distribution for continuous variables. The right eye of the patients who had ICRS implanted in both eyes was selected for statistical analysis. The Wilcoxon signed-rank test (a non-parametric statistical test) was used to analyse the differences in visual acuity with the best spectacle-corrected value and data from visual quality tests, before and after CScL fitting, as well as after first fitting CScL and after 1 year of CScL wear. All visual acuities were converted to logMAR (logarithm of the minimum angle of resolution) for statistical analysis. The threshold for statistical significance was taken as $p < 0.05$.

Table 1
Criteria for success in fitting corneo-scleral contact lenses.

Parameters	Complete Success	Partial Success	Unacceptable
-Visual Acuity with CL as regards BSCVA	Improving two decimal lines or more	Improving one decimal line or equal	Worse
-CL wear time	> 10 h	10–8 h	< 8 h
-Subjective comfort	> 3	3	< 3
-Subjective visual quality	> 3	3	< 3

CL, contact lenses; BSCVA, best spectacle-corrected visual acuity; Subjective comfort scale (1, very uncomfortable; 2, uncomfortable; 3, neither uncomfortable nor comfortable; 4, comfortable; and 5, very comfortable); Subjective visual quality scale (1, very poor; 2, poor; 3, neither poor nor favourable; 4, favourable; and 5, very favourable).

Table 2
Demographic data of the 27 keratoconic patients with intracorneal ring segment implants.

Parameters		Patients (%)
Sex	Male	18 (66.67)
	Female	9 (33.33)
Age	< 20 years	2 (7.41)
	21–40 years	22 (81.48)
	41–60 years	3 (11.11)
Refractive error	Hyperopia (0.00 to +10.00 D)	3 (11.11)
	Low myopia (−0.25 to −6.00 D)	21 (77.78)
	Medium myopia (−6.25 to −10.00 D)	3 (11.11)
Average central keratometry	≤48 D (Degree I AK)	18 (66.67)
	48 to 53 D (Degree II AK)	7 (25.92)
	53 to 55 D (Degree III AK)	1 (3.70)
	> 55 D (Degree IV AK)	1 (3.70)
Corneal astigmatism	0.00–2.00 D	9 (33.33)
	2.25–4.00 D	8 (29.63)
	4.25–6.00 D	5 (18.52)
	> 6.00 D	5 (18.52)

AK, the Amsler-Krumeich classification.

3. Results

Table 2 shows the demographic data of the participants. The mean ± SD age of the 18 men and 9 women was 30.4 ± 9 years and they were all Caucasian.

Table 3 shows the mean ± SD of the spherical equivalent with the best spectacle-corrected value, corneal astigmatism, average central keratometry, endothelial-cell count, central corneal thickness, ocular aberrometry and contrast sensitivity data prior to fitting the CScL, as well as the parameters of the CScL (the back optic zone radius, total diameter, and lens power) fitted.

An average of 2.63 ± 0.74 visits (range 2–4) were needed to complete the fitting process and 1.41 ± 0.57 lenses per eye (range 1–3) until considered optimal for dispensing. The mean wearing time was 11.78 ± 3.93 consecutive hours a day (range 4–17). A percentage of 74.1% (20 of 27 eyes) wore these contact lenses ≥10 consecutive hours a day. In addition, high levels of subjective comfort (4, comfortable and 5, very comfortable) were reported in 66.66% (18 of 27 eyes), as well as subjective visual quality (4, favourable and 5, very favourable) in 70.37% of eyes (19 of 27 eyes). Therefore, complete success (see Table 1) was achieved in 51.85% of eyes (14 of 27 eyes), partial success in 29.62% of eyes (8 of 27 eyes); the result, however, was deemed unacceptable in 5 out of 27 eyes.

The mean ± SD of the logMAR visual acuity before (with the best spectacle-corrected value) and after fitting CScL was 0.22 ± 0.17 (range 0.5–0.0) and 0.00 ± 0.12 (range 0.2 to −0.1), respectively; statistically significant differences were found ($p < 0.001$). Visual acuity improved two decimal lines or more with respect to the best spectacle-corrected value in 92.6% of eyes (25 of 27 eyes).

Fig. 2 shows the mean ± SD of ocular aberrations before and after fitting CScL. Statistically significant differences were found in all ocular

Table 3
Mean ± SD of the clinical outcomes of the 27 keratoconic eyes with intracorneal ring segment implants before fitting corneo-scleral contact lenses and the parameters of these lenses after being fitted.

Parameters		Mean ± SD	Range
Clinical	Spherical equivalent with BSCVA (D)	−3.44 ± 2.85	+3.50 to −9.12
	Corneal astigmatism (D)	3.84 ± 2.74	0.50–10.90
	Average central keratometry (D)	46.54 ± 4.19	37.90–56.10
	Endothelial-cell count (cell/mm^2)	2509 ± 474	1712–3779
	Central corneal thickness (μm)	451 ± 43	343–535
Contrast sensitivity	A (1.5 cycles/degree; scores)	2.4 ± 0.7	0–5
	B (3 cycles/degree; scores)	2.4 ± 1.4	0–5
	C (6 cycles/degree; scores)	2.2 ± 2.8	0–6
	D (12 cycles/degree; scores)	2.3 ± 2.1	0–6
	E (18 cycles/degree; scores)	2.4 ± 2.8	0–6
Ocular aberrations	Vertical coma (μm)	1.45 ± 0.95	0.21–3.26
	Spherical (μm)	0.92 ± 0.75	0.11–3.23
	Other HOAs (μm)	1.72 ± 1.04	0.55–4.18
	Total HOAs (μm)	2.62 ± 1.31	0.80–5.59
Contact lens	BOZR (mm)	7.48 ± 0.48	6.40–8.20
	Total diameter (mm)	12.91 ± 0.29	12.60–13.50
	Power (D)	−2.85 ± 2.43	+3.5 to −7

BSCVA, the best spectacle-corrected visual acuity; HOAs, high-order aberrations; BOZR, back optic zone radius.

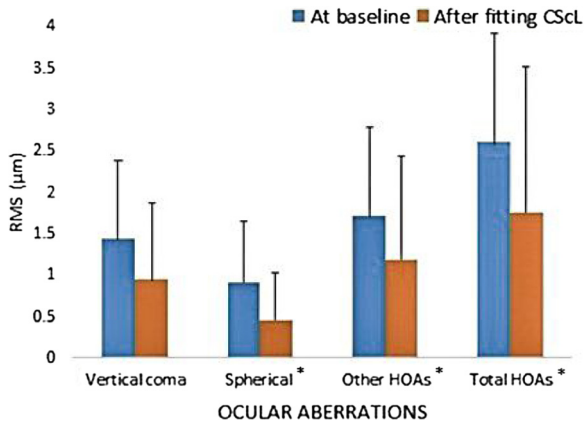

Fig. 2. Differences in ocular aberrations before and after fitting corneo-scleral contact lenses (27 keratoconic eyes with intracorneal ring segment implants; a pupil diameter of 6 mm was used for evaluation).
*Statistically significant differences.

aberrations ($p < 0.05$) except vertical coma aberration ($p = 0.059$). The total HOAs decreased 33% (2.62 μm initially and 1.75 μm after fitting CScL; $p < 0.009$). Fig. 3 shows the average ± SD of spatial frequencies (1.5, 3, 6, 12 and 18 cycles/degree) in contrast sensitivity with the best spectacle-corrected value and after fitting the CScL. Statistically significant differences were found in all spatial frequencies (all $p < 0.05$).

After a one-year follow-up, the parameters of corneal integrity and visual quality showed no statistically significant differences with respect to the initial fitting (see Table 4). In addition, subjective visual quality and comfort ratings, together with prolonged usage times were maintained. No adverse ocular events were found during this period.

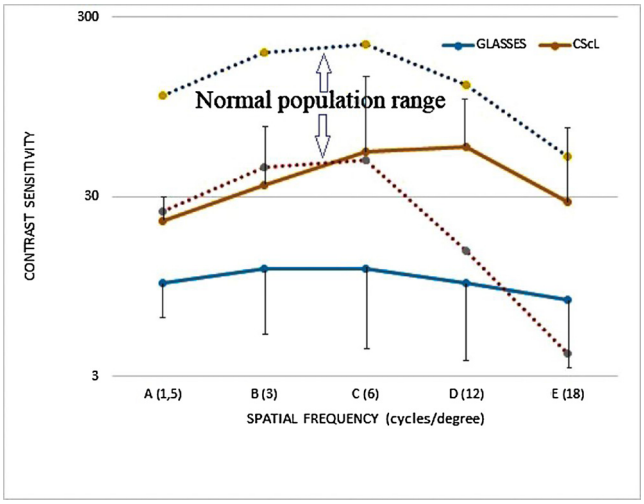

Fig. 3. Differences in spatial frequencies before (with the best spectacle-corrected value) and after fitting corneo-scleral contact lenses (27 keratoconic eyes with intracorneal ring segment implants). Statistically significant differences were found in all the spatial frequencies.

4. Discussion

There are few studies in the scientific literature on fitting corneo-scleral or scleral contact lenses in keratoconic eyes with ICRS placement. Moreover, they only report findings on a small number of eyes in which such lenses had been fitted. For example, Romero-Jiménez and Flores-Rodríguez described nine keratoconic eyes with ICRS implants out of 30 eyes with irregular corneas, which were fitted with a semi-scleral (or corneo-scleral) contact lens (diameter around 14.5 mm) [22]. Alipur et al. fitted mini-scleral design lenses (diameter of 15.8 mm) successfully in nine eyes in their series [21]. The authors suggested that these lenses were an excellent option in cases with unsatisfactory outcomes with spectacles or corneal RGP contact lenses. In a recent study fitting a large diameter scleral lens in two eyes (diameter of 18 and 18.5 mm), the authors suggested that these lenses may be tried when patients are intolerant to corneal RGP or soft contact lenses [19]. In the present study, a corneo-scleral contact lens was fitted as an alternative option to treat keratoconus with ICRS placement (diameter 12.60–13.50 mm). They could be considered when other types of contact lenses are not successfully fitted or present intolerance, which sometimes occurs with corneal RGP lenses, soft contact lenses or full scleral lenses (e.g. when insertion is difficult). These lenses were successfully fitted in keratoconic eyes without ICRS implants [30], however little was known as to what degree of improvement in visual quality they can provide when ICRS have been implanted.

Previous studies report that although good visual acuity may be achieved with RGP lenses on irregular corneas, visual quality could be decreased [32,33]. The outcomes of this study show that visual acuity improved significantly, that similar values to previous studies were achieved in which the same CScL were fitted in keratoconic eyes without ICRS implants [30] and on irregular corneas of post-LASIK eyes [29]. However, when assessing visual quality in these previous studies, the outcomes in post-LASIK eyes were better than in keratoconic eyes. These differences could be attributed to factors such as posterior corneal surface irregularity, among others, which is more affected in keratoconic eyes [30]. It should be noted that after ICRS implantation, significant changes in the mid-periphery posterior corneal surface occurs, therefore these changes may have significant induced effects on total aberrometry, and consequently visual quality may be decreased. A previous study by Alipur et al. found that total HOAs significantly decreased after fitting mini-scleral lenses, although residual HOAs still remained high [21]. A limitation of this study is its small sample size,

Table 4
Differences in corneal integrity, contrast sensitivity scores and ocular aberration values between the initial fitting and after 1 year wearing corneo-scleral contact lenses (27 keratoconic eyes with intracorneal ring segment implants).

Parameters		Initial fitting Mean ± SD	After 1 year Mean ± SD	P value[a]
Corneal integrity	Km (D)	46.54 ± 4.19	47.29 ± 4.55	0.121
	ECC (cell/mm^2)	2509 ± 474	2499 ± 388	0.821
	CCT (μm)	451 ± 43	456 ± 44	0.329
Contrast sensitivity	A (1.5 cycles/degree; scores)	4.5 ± 0.7	4.8 ± 0.7	0.465
	B (3 cycles/degree; scores)	4.6 ± 1.4	4.7 ± 1.4	1
	C (6 cycles/degree; scores)	4.4 ± 2.1	4.6 ± 2.1	0.066
	D (12 cycles/degree; scores)	5.1 ± 1.4	5.2 ± 1.4	0.445
	E (18 cycles/degree; scores)	5.1 ± 2.1	5.4 ± 2.1	0.785
Ocular aberrations	Vertical coma (μm)	0.92 ± 1.12	0.88 ± 1.03	0.506
	Spherical (μm)	0.47 ± 0.68	0.45 ± 0.61	0.587
	Other HOAs (μm)	1.22 ± 1.45	1.22 ± 1.20	0.694
	Total HOAs (μm)	1.75 ± 1.81	1.72 ± 1.60	0.121

Km, average central keratometry; ECC, endothelial-cell count; CCT, central corneal thickness; HOAs, high-order aberrations.
[a] P value from the Wilcoxon signed-rank test.

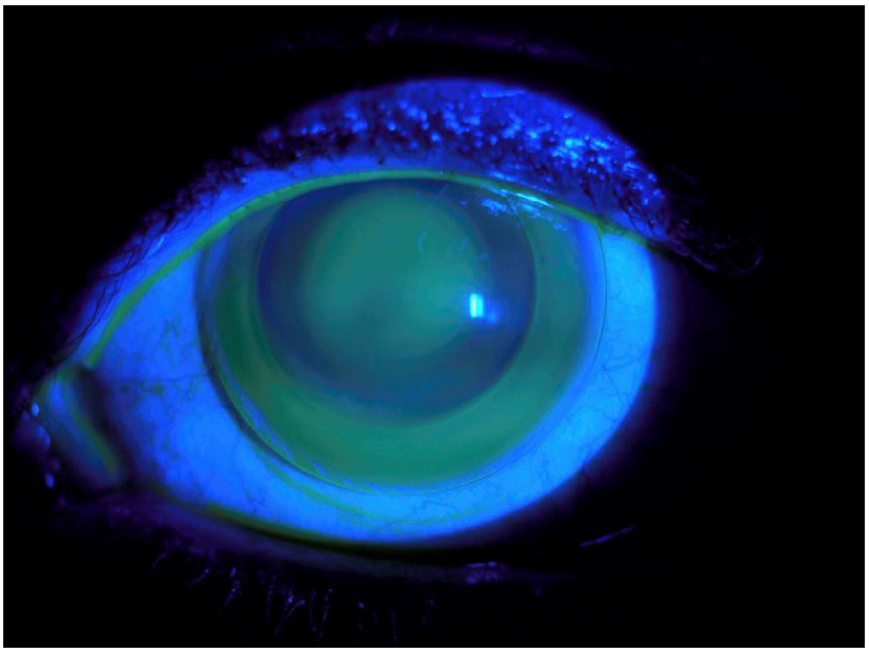

Fig. 4. Corneoscleral contact lens fitted in a keratoconic eye with two Keraring intracorneal ring segments in this study.

therefore the amount of residual HOAs and their effects on visual quality after fitting RGP lenses in keratoconic eyes with ICRS implants are not sufficiently known.

In the present study, the outcomes show that objective and subjective visual quality tests improved after CScL fitting, although to a lesser extent in ocular aberrometry. In contrast to previous studies fitting the same CScL on irregular corneas of post-LASIK [29] and keratoconic eyes without ICRS placement [30], the reduction in percentages of total HOAs was worse in keratoconic eyes with ICRS implants, (78% decrease for post-LASIK eyes, 55% for keratoconic eyes without ICRS placement, and 33% in keratoconic eyes with ICRS implants) therefore, the average residual HOAs was higher (0.24 μm for post-LASIK eyes, 0.73 μm for keratoconic eyes without ICRS placement, and 1.75 μm in keratoconic eyes with ICRS implants).

The average residual HOAs in this study after fitting CScL are significantly higher than in the normal healthy population between the ages of 30 and 39 years and with a pupil diameter of 6 mm (1.75 vs 0.45 μm, respectively) [34]. Fig. 2 shows that the other HOAs and vertical coma aberration were the main residual HOAs found after fitting CScL, which concurs with the outcomes of our previous study without ICRS placement [30]. However, significant differences in these ocular aberrations between the two studies were observed, such aberrations increasing when ICRS were implanted (an average of 0.32 vs 1.19 μm for other HOAs; and 0.45 vs 0.9 μm for vertical coma aberration). Therefore, effects induced by ICRS placement on the corneal posterior surface could mainly affect visual quality.

Previous studies report correlations between high residual HOAs with a decrease in contrast sensitivity in keratoconic eyes [32,33]. In agreement with the residual HOAs found in the present study, the contrast sensitivity test showed slightly lower values than normal population ranges, in particular for low and intermediate frequencies (see Fig. 3). However, 70.37% of patients reported a favourable or very favourable subjective visual quality after having CScL lenses fitted. These subjective success results could be due to factors such as a significant decrease in vertical coma aberration after fitting CScL (an average of 35%). It should be noted that lower order and more central aberrations in the Zernike table (such as coma and spherical aberrations for HOAs) affect image quality largely [35]; therefore, patients can report a significant subjective visual improvement [36].

In relation to the fitting procedure of the CScL in these cases of keratoconic eyes with ICRS implants, although it would appear to be more difficult than without such implants (due to the additional corneal

irregularity induced by them), a successful fit can be achieved with an appropriate back optic zone radius and peripheral curve (see Fig. 4). In comparison with keratoconic eyes without ICRS placement, an average in a slight steepness in the back optic zone radius (around 0.05 mm) was found [30]. The aim in these cases is to achieve a greater corneal clearance to avoid touch (or excessive pressure) of the lens on the mid-periphery steepening zone caused by ICRS implantation and the apical zone. The number of visits and the number of lenses that had to be ordered to achieve a precise fit and subjective comfort were similar to those necessary when treating eyes without ICRS implants [30]. Finally, the number of hours wearing the lens per day were slightly fewer in the keratoconic eyes with ICRS implants than without them [30].

After one year of CScL wear, no significant adverse events of the cornea were observed. There was no staining in compromised areas, such as limbal, mid-periphery or apical corneal zones, nor was there any apparent corneal physiological impairment, such as corneal oedema. No variations in corneal integrity, such as the endothelial-cell count and central corneal thickness, were found with respect to the initial fitting. Moreover, there were no significant adverse effects on the scleral zone around the cornea, such as morphological changes in the conjunctiva, which could be due to compression of the lens. The visual quality, number of hours wearing the lens, and subjective comfort were also maintained.

The main limitation of this study was the small sample size. Future studies with a greater sample size when fitting RGP (corneo-scleral or full scleral) contact lenses are needed to confirm our outcomes. Also, it should be noted that the outcomes of this study are not strictly comparable with our previous studies fitting the same contact lens in other irregular corneas.

In conclusion, according to the outcomes of this study, fitting corneo-scleral contact lenses may be an alternative feasible option for keratoconic eyes with ICRS placement, providing an improvement in subjective visual quality (70.37% of patients in this study). In addition, they proved to be safe and healthy and provided optimal comfort and prolonged usage times. In only 5 out of 27 eyes evaluated, the fit was considered unacceptable (visual acuity did not improve or the lens was not comfortable). An alternative option to improve visual quality when patients are unsatisfied with these CScL could be customised contact lenses. However, these lenses are not easily available and may lead to significant cost in time and resources for patients and clinicians [28,37].

Conflicts of interest or financial support

The authors declare that there is no conflict of interest.

References

[1] Y.S. Rabinowitz, Intacs for keratoconus, Int Ophthalmol Clin 46 (3) (2006) 91–103.
[2] J. Colin, B. Cochener, G. Savary, F. Malet, Correcting keratoconus with intracorneal rings, J Cataract Refract Surg 26 (89) (2000) 1117–1122.
[3] J. Colin, B. Cochener, G. Savary, F. Malet, D. Holmes-Higgin, Intacs insert for treating keratoconus: one-year results, Ophthalmology 108 (8) (2001) 1409–1414.
[4] C.S. Siganos, G.D. Kymionis, N. Kartakis, M.A. Theodorakis, N. Astyrakakis, I.G. Pallikaris, Management of keratoconus with Intacs, Am J Ophthalmol 135 (1) (2003) 64–70.
[5] B.S. Boxer Wachler, J.P. Christie, N.S. Chandra, B. Chou, T. Korn, R. Nepomuceno, Intacs for keratoconus, Ophthalmology 110 (5) (2003) 1031–1040.
[6] J. Colin, F. Malet, Intacs for the correction of keratoconus: two-year follow up, J Cataract Refract Surg 33 (1) (2007) 69–74.
[7] D.P. Piñero, J.L. Alio, Intracorneal ring segments in ectatic corneal disease - a review, Graefes Arch Clin Exp Ophthalmol 38 (2) (2010) 154–167.
[8] G. Ferrara, L. Torquetti, P. Ferrara, J. Merayo-Lloves, Intrastromal corneal ring segments: visual outcomes from a large case series, Graefes Arch Clin Exp Ophthalmol 40 (5) (2012) 433–439.
[9] L. Fernández-Vega Cueto, C. Lisa, A. Poo-López, D. Madrid-Costa, J. Merayo-Lloves, J.F. Alfonso, Intrastromal corneal ring segment implantation in 409 paracentral keratoconic eyes, Cornea 35 (11) (2016) 1421–1426.
[10] P.S. Mandathara, F.J. Stapleton, M.D. Willcox, Outcome of keratoconus management: review of the past 20 years' contemporary treatment modalities, Eye Contact Lens 43 (3) (2017) 141–154.
[11] D.J. Schanzlin, R.L. Abbott, P.A. Asbell, K.K. Assil, T.E. Burris, D.S. Durrie, et al., Two-year outcomes of intrastromal corneal ring segments for the correction of myopia, Ophthalmology 108 (9) (2001) 1688–1694.
[12] O.O. Uçakhan, A. Kanpolat, O. Ozdemir, Contact lens fitting for keratoconus after Intacs placement, Eye Contact Lens 32 (2) (2006) 75–77.
[13] L.B. Moreira, R.A. Bardal, L.R. Crisigiovanni, Contact lenses fitting after intracorneal ring segments implantation in keratoconus, Arq Bras Oftalmol 76 (4) (2013) 215–217.
[14] M. Kumar, R. Shetty, R.S. Kumar, S. Nagaraj, B. Shetty, Use of wavefront imaging technology to demonstrate improvement in corneal aberrations using Piggyback contact lens in a keratoconus eye with intrastromal corneal ring segment implantation: a case report, Eye Contact Lens 42 (3) (2016) 12–16.
[15] K.A. Smith, J.D. Carrell, High Dk Piggyback contact lenses over INTACTS for keratoconus: a case report, Eye Contact Lens 34 (4) (2008) 238–241.
[16] K. Dalton, L. Sorbara, Fitting an MSD (mini scleral design) rigid contact lens in advanced keratoconus with Intacs, Cont Lens Anterior Eye 34 (6) (2011) 274–281.
[17] I. Baran, J.A. Bradley, F. Alipour, P. Rosenthal, H.G. Le, D.S. Jacobs, PROSE treatment of corneal ectasia, Cont Lens Anterior Eye 35 (5) (2012) 222–227.
[18] R.L. Nepomuceno, B.S. Boxer Wachler, B.A. Weissman, Feasibility of contact lens fitting on keratoconus patients with INTACS inserts, Cont Lens Anterior Eye 26 (4) (2003) 175–180.
[19] V.M. Rathi, P.S. Mandathara, S. Dumpati, V.S. Sangwan, Scleral lens after intracorneal ring segments in patients withkeratoconus, Cont Lens Anterior Eye 41 (2) (2018) 234–237, https://doi.org/10.1016/j.clae.2017.10.013.
[20] E.G. Kramer, E.L. Boshnick, Scleral lenses in the treatment of post-LASIK ectasia and superficial neovascularization of intrastromal corneal ring segments, Cont Lens Anterior Eye 38 (4) (2015) 298–303.
[21] F. Alipour, F. Rahimi, M.N. Hashemian, Z. Ajdarkosh, R. Roohipoor, M. Mohebi, Mini-scleral contact lens for management of poor visual outcomes after Intrastromal corneal ring segments implantation in keratoconus, J Ophthalmic Vis Res 11 (3) (2016) 252–257.
[22] M. Romero-Jiménez, P. Flores-Rodríguez, Utility of a semi-scleral contact lens design in the management of the irregular cornea, Cont Lens Anterior Eye 36 (3) (2013) 146–150.
[23] J. Carballo-Alvarez, M.C. Puell, R. Cuiña, D. Diaz-Valle, J.M. Vazquez, J.M. Benitez-Del-Castillo, Soft contact lens fitting after intrastromal corneal ring segment implantation to treat keratoconus, Cont Lens Anterior Eye 37 (5) (2014) 377–381.
[24] F.J. Fernández-Velázquez, M.J. Fernández-Fidalgo, Feasibility of custom-made hydrogel contact lenses in keratoconus with previous implantation of intracorneal ring segments, Cont Lens Anterior Eye 38 (5) (2015) 351–356.
[25] K. Gumus, N. Kahraman, A new fitting approach for providing adequate comfort and visual performance in keratoconus: soft hydrocone (Toris K) lenses, Eye Contact Lens 42 (4) (2016) 225–230.
[26] G. Carracedo, J. Canales, P. Gonzalez, A. Recchioni, C. Carpena-Torres, J. Carballo-Álvarez, The effect of soft contact lens thickness in visual function after intracorneal ring segments surgery, Cont Lens Anterior Eye 41 (2) (2018) 180–186.
[27] G. Gemoules, Therapeutic effects of contact lenses after refractive surgery, Eye Contact Lens 31 (1) (2005) 12–22.
[28] R. Sabesan, L. Johns, O. Tomashevskaya, D.S. Jacobs, P. Rosenthal, G. Yoon, Wavefront-guided scleral lens prosthetic device for keratoconus, Optom Vis Sci 90 (4) (2013) 314–323.
[29] E. Porcar, E. España, J.C. Montalt, J.I. Benlloch-Fornés, C. Peris-Martínez, Post-LASIK visual quality with a corneoscleral contact lens to treat irregular corneas, Eye Contact Lens 43 (1) (2017) 46–50.
[30] J.C. Montalt, E. Porcar, E. España, C. Peris-Martínez, Visual quality with corneoscleral contact lenses for keratoconus management, Cont Lens Anterior Eye 44 (4) (2018) 351–356.
[31] I. Ortenberg, S. Behrman, W. Geraisy, I.S. Barequet, Wearing time as a measure of success of scleral lenses for patients with irregular astigmatism, Eye Contact Lens 39 (6) (2013) 381–384.
[32] R.H. Wei, W.B. Khor, L. Lim, D.T. Tan, Contact lens characteristics and contrast sensitivity of patients with keratoconus, Eye Contact Lens 37 (5) (2011) 307–311.
[33] B. Yang, B. Liang, L. Liu, M. Liao, Q. Li, Y. Dai, et al., Contrast sensitivity function after correcting residual wavefront aberrations during RPG lens wear, Optom Vis Sci 91 (10) (2014) 1271–1277.
[34] A.S. Bruce, L.J. Catania, Clinical applications of wavefront refraction, Optom Vis Sci 91 (10) (2014) 1278–1286.
[35] R.A. Applegate, E.J. Sarver, V. Khemsara, Are all aberrations equal? J Refract Surg 18 (5) (2002) 556–562.
[36] R.G. Chalita, R.R. Krueger, Wavefront aberrations associated with the Ferrara intrastromal corneal ring in a keratoconic eye, J Refract Surg 20 (6) (2004) 823–830.
[37] J.D. Marsack, A. Ravikumar, C. Nguyen, A. Ticak, D.E. Koenig, J.D. Elswick, et al., Wavefront-guided scleral lens correction in keratoconus, Optom Vis Sci 91 (10) (2014) 1221–1230.